

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

THIS PAGE BLANK (USPTO)



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 5/445, B26F 1/36		A1	(11) International Publication Number: WO 00/51533 (43) International Publication Date: 8 September 2000 (08.09.00)
(21) International Application Number: PCT/NO00/00077 (22) International Filing Date: 2 March 2000 (02.03.00) (30) Priority Data: 19991084 4 March 1999 (04.03.99) NO (71)(72) Applicant and Inventor: ANDERSEN, Svein, Jacob [NO/NO]; Opalveien 15, N-4070 Randaberg (NO). (74) Agents: EIVIND, Håmsø et al.; Håmsø Patentbyrå Ans, P.O. Box 171, N-4302 Sandnes (NO).		(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
		Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> <i>In English translation (filed in Norwegian).</i>	
<p>(54) Title: DEVICE IN CONNECTION TO HOLE PUNCHING PLIERS ARRANGED TO PUNCH HOLES IN A SKIN PROTECTION PLATE FOR A STOMA BAG</p> <p>(57) Abstract</p> <p>A pair of hole punching pliers, so-called stoma pliers, is arranged to punch a hole in a skin protection plate for a stoma bag. The hole punching remedies of the pliers consist of a hole socket (16) and a holding-up plate (18) for the same. During the punching, a plastic skin protection plate is located between the hole socket (16) and the opposing surface of the holding-up plate (18), as the free, outer cutting/punching edge (22) of the hole socket (16) after the completion of the punching abuts directly on said opposing holding-up plate surface. To achieve an optimal punching operation, which is dependant upon the hole socket's (16) outer punching edge part (22) being placed maximally perpendicularly on said holding-up plate surface, at the same time as this surface should be able to dislocate (turning eccentrically) in relation to the wearing effect of said outer punching edge part on the surface of the holding-up plate by its abutments against same at the completion of each hole punching, at least the hole socket (16) has pivotal bearing around a lateral axis (24), which is arranged perpendicularly on its symmetrical axis (26), which in its closed position at the completion of each hole punching runs eccentrically in relation to the symmetrical axis (30) of the holding-up plate (18), which said symmetrical axis forms the pivotal axis of the holding-up plate (18).</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CII	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

DEVICE IN CONNECTION TO HOLE PUNCHING PLIERS ARRANGED TO
PUNCH HOLES IN A SKIN PROTECTION PLATE FOR A STOMA BAG

The present invention concerns a device connected to hole
punching pliers, which are arranged to punch holes in a
protective plate for a stoma bag, and where the nose of the
pliers is equipped with co-operating hole punching remedies
in the shape of a hole socket and a holding-up plate for said
socket.

A considerable number of the population, approximately 4
0/00 or a good 13000 persons in Norway alone, are in a
situation of having been stoma operated and having to live
with laid out intestine. The remedy used by a stoma operated
person to handle the faeces from the intestine end, which has
been laid out from the body, is a stoma bag. The bag is
secured to the body by means of a skin protecting plate where
holes have been made to introduce the intestine end into the
bag. The plate is fitted with a glue part on the skin side,
so that it may be secured to the body. The size of each
individual's intestine end will vary with time, meaning the
hole has to be constantly changed. The difference is normally

between 1 and 3 mm. Likewise, the size of the intestine differs from person to person.

Thus, the plate may not be fitted with a uniform opening for the intestine end. The individual may also not use plates having identical holes, as the size of the intestine may have altered once the plate has to be changed. Some persons change plate and bag as often as 1-3 times daily, while for others 2-3 weekly changes may be sufficient. The difference in intestine size is assumedly the reason why the suppliers promoting bags and plates prescribe the hole be cut with scissors.

In practice it turns out that the cutting of holes with scissors leads to great disadvantages to most users. One disadvantage is due to the fact that the plate is relatively thick in the area where it is to be cut, meaning the hole will have a jagged edge and accordingly not fit tightly enough around the intestine end.

The faeces are cauterising and cause discomfort, especially sore skin, if an uneven cut leads to skin coming into contact with faeces. It is therefore not unusual that several plates have to be cut before an acceptable result is achieved. Alternatively, the leaks around the intestine end, resulting from an unevenly cut hole, may be sealed by means of a paste.

As it is impossible to control the defecation, it is preferable that the changing of plate and bag be as rapid as possible.

Before a new bag and plate can be fitted, the intestine has to be controlled for size, which can first be effectuated after the removal of the used bag and plate. It is thus hard to avoid contact between faeces and naked skin or clothing, especially when knowing that the most experienced users need up to 10 minutes to cut a suitable hole. Elderly users may have trouble with the cutting due to shaking hands etc. The hole may also not be cut to fit too tightly, as it causes discomfort when the intestine end is squeezed. Moreover, many users feel mental unease caused by the dread of the discomfort of a wrongly adjusted hole.

As it is not unusual that 2-3 plates have to be cut before the hole is as required, it is evident that the cutting also has unwanted economic results.

It is true that pliers based on hole punching operations carried out more or less in one operation, instead of cutting, are known, cf. e.g. U.S. patent no. 4.817.287. These known hole punching pliers are generally constructed as a pair of scissors having two elements which are pivotally connected to each other by means of a cross member, and where the two parts of the pivotal elements positioned on one side of the member create handles, while the free ends of the element parts on the other side of the member carry a so-called hole socket and a holding-up plate for the hole socket at their free end, as the punching of holes in a suitable plastic material for the skin protection plate obviously takes place with this placed between the hole socket and the holding-up plate.

In these known hole making pliers the hole socket, as well as the holding-up plate are secured to the end of the respective

pivotal pliers. In such a constructive embodiment of the hole making pliers one pair of pliers is needed for each hole dimension.

It is furthermore a disadvantage concerning these known hole making pliers that the hole socket and the holding-up plate have to be dimensioned with precision and placed very accurately in relation to each other to achieve that the free working edge circumference of the hole socket hits the opposed surface of the holding-up plate as perpendicularly as possible, thus to secure cleanly cut hole edges in the skin protection plates of the stoma bags.

Concerning the above described known hole making pliers, an embodiment is shown in which a circumferential slot is formed in the holding-up plate, being nearly complementarily shaped to the outer, free cutting edge part of the hole socket. Also in other embodiments of the pliers, of this and similar natures, - having one and the same dimension of pliers - the free cutting edge of the hole socket will hit the opposed surface of the holding-up plate almost identically with every hole making operation, so that the holding-up plate is constantly worn in the same place, and is damaged.

The scope of the invention has i.a. been to remedy, or to a substantial degree reduce, the defects, the disadvantages and the limitations of application in known techniques, and thus provide a pair of hole punching pliers where the necessary measures are taken, partly to facilitate an exchange of hole sockets having different diameters, partly to secure correct adaptation between hole socket and holding-up plate during each hole punching operation, and partly to postpone damaging

wear on the holding-up plate, thus providing it with an extended useful duration.

To realise the above mentioned scope, the invention distinguishes itself in the features designated in the characterizing clause of Claim 1.

According to the invention the hole socket and/or the holding-up plate are placed restrictedly pivotally around separate axes stretching perpendicularly on the symmetrical axis of the hole socket, respectively of the holding-up plate. This secures the correct adaptation of the free cutting/ punching edge area of the hole socket in relation to the opposed holding-up surface, that is, with said free cutting edge area directed perpendicularly towards said holding-up plate surface, with the intermediate skin protection plate.

To distribute the wear from the free cutting edge of the hole socket onto the holding-up plate, it is convenient for the holding-up plate to have a freely pivotal bearing around an axis which runs parallel to its symmetrical axis, and eccentrically in relation to the symmetrical axis. Thus the abutment of the outer, free cutting edge of the hole socket on the holding-up plate will relocate from one hole punching operation to the next, so that the said wear will be distributed over the holding-up plate.

The fact that the holding-up plate is freely pivotal also means that users who do not possess the strength required to push the hole socket through the skin protection plate, may rotate the holding-up plate once the pliers are squeezed, and may thus achieve a cutting effect.

A non-limiting example of preferred embodiments are explained below with reference to the accompanying illustrations, where:

Figures 1 and 2 show a first embodiment of a pair of stoma pliers shaped according to the invention, while figures 3-5 show a second embodiment where

Fig. 1 shows a side view of the stoma pliers in open position;

Fig. 2, which corresponds to fig.1, shows the stoma pliers in closed position;

Fig. 3 corresponds to fig. 1, but shows a second embodiment which in particular concerns the bearing of the holding-up plate, which is shown in cross section, together with the outer part of the hole socket;

Fig. 4 shows the stoma pliers of fig. 3 in closed position;

Fig. 5 is sketch of a sectional view on a larger scale, showing the bearing of the holding-up plate.

We firstly refer to figures 1 and 2, in which the number of reference 10 generally indicates a pair of so-called stoma pliers, whose parts are denoted by 12.

Partly, a so-called hole socket (cutting head) 16 is pivotally arranged to the free ends of the pliers' nose, partly a holding-up plate 18 for the hole socket 16 is arranged to said free ends. On the surface facing the hole

socket 16 the holding-up plate is equipped with a thin layer of plastic material 18b. In a plastic skin protecting plate (not shown), belonging to a stoma bag (also not shown), a hole will be punched to facilitate the introduction of the intestine end into the stoma bag. As the size of the intestine end will vary with time for each patient, the hole dimension has to be altered frequently.

This may be performed in the known way by inserting the skin protection plate between hole socket 16 and holding-up plate 18 in the position shown in fig. 1, and then by a normal squeezing movement of the pliers' handles 20 to bring together hole socket 16 and holding-up plate 18 with the intermediate plastic plate 18b, whereby the sharp, free, peripheral cutting/punching edge 22 of the hole socket 16 cuts through said skin protection plate making a hole in it, which corresponds to the circumferential shape of said cutting/punching edge 22. The punching process is completed when the outer, free cutting/punching edge 22 of the hole socket abuts on the opposed surface of the holding-up plate 18b, without any intermediate plastic material from the skin protection plate. Both the hole socket 16 and the holding-up plate 18 are screwably connected to each respective end of the pliers' nose 14, so that they may easily be replaced for another dimension.

In order to achieve optimal adaptation between hole socket 16 and holding-up plate 18, at least one of these hole punching remedies 16, 18 has pivotal bearing around an axis which is perpendicular on the symmetrical axis of the respective hole punching remedy (16, 18).

According to the embodiment according to figures 1 and 2 the hole socket has thus a bearing around a lateral axis 24, which is perpendicular on the symmetrical axis 26 of the hole socket 16. In a corresponding way the holding-up plate 18 has a bearing around a lateral axis 28 which is perpendicular on the symmetrical axis 30 of the holding-up plate 18.

In addition to optimising the adaptation between the hole punching remedies, whereby the hole socket 16 enters into hole punching position with its cutting/punching edge 22 directed perpendicularly onto the skin protecting plate (not shown), which abuts on the holding-up plate during the hole punching operation, the pivotal bearing of the hole punching remedies 16 and 18 in addition facilitates the simple replacement of the respective remedy.

The embodiment according to figures 3-5 substantially corresponds with the embodiment shown in figures 1 and 2, except for the bearing of the holding-up plate 18. Concerning parts of the two embodiments which are identical or functionally similar, the same numbers of reference are used. For the holding-up plate, which in figures 3-5 has a different bearing and correspondingly deviating function in relation to the holding-up plate 18 of figures 1 and 2, the indicating reference 18c is used.

In the embodiment according to figures 3 and 4, it is only the hole socket 16 which has pivotal bearing around a lateral axis 24 perpendicularly on its symmetrical axis 26. With regard to the mentioned orientational adaptation between the hole punching remedies, the hole socket 16 and the holding-up plate 18c, it is as mentioned sufficient that one of these remedies, e.g. the hole socket 16 (or the holding-up plate

18c) performs this pivotal ability in relation to the other remedy.

The holding-up plate 18c in the embodiment according to figures 3-5 has a symmetrical axis 30 running eccentrically with regard to the corresponding axis 26 of the hole socket 5 in the hole punching position.

Moreover, the holding-up plate has pivotal bearing around this symmetrical axis 30. This is effected by a bolt 32 being screwed through an internally threaded boring 34 in one in the pliers' nose part 14 inserted block-like part 35, fig. 5, 10 with its short externally threaded end part 36, which after the screwing-in of the bolt 32 in the boring 34 has ended in an unthreaded cavity 38. The opposite part 40 of the bolt 32 is secured in a known way to the holding-up plate 18a, which 15 is fitted with an overlaying glued-on or otherwise attached holding-up plate 18b.

When the holding-up plate 18b, 18c is pivotal around an axis 30 which is eccentric in relation to the axis of the hole socket 16, will the circular abutment of the hole socket 16 20 against the holding-up plate 18b, through the latter's mutually deviating pivotal positions in relation to the hole socket 16 from one punching operation to the next, be unevenly distributed over that holding-up plate surface which during the punching is facing the peripheral cutting/punching edge of the hole socket. 25

To facilitate potential turning of the holding-up plate 18, 18c simultaneously with the squeezing together of the pliers, the periphery of the holding-up plate may be fluted or serrated.

CLAIMS

1. Device in connection to hole punching pliers arranged to
punch holes in a skin protection plate for a stoma bag,
comprising two pliers' parts (14, 20 and 14, 20) which
are pivotally connected by means of an intermediate
member (12), where the pliers' parts (20) to one side of
the member (12) form the handle of the pliers, while the
free ends of the pliers' nose (14) each carry a
respective hole punching remedy in the shape of a hole
socket (16) and a holding-up plate (18) for said socket,
and where the hole is punched in a skin protection plate
when this is positioned between the outer, free
cutting/punching edge (22) of the hole socket (16), and
the opposing surface of the holding-up plate (18),
characterized in that the hole socket
(16) and/or the holding-up plate (18) having a pivotal
bearing around a lateral axis (24, respectively 28),
which is vertically positioned on the symmetrical axis
(26, respectively 30) of the hole socket (16),
respectively of the holding-up plate (18).
2. Device in connection to hole punching pliers according to
claim 1, characterised in that the
symmetrical axis (26) of the hole socket (16) and the
symmetrical axis (30) of the holding-up plate (18) are
substantially coinciding at the completion of hole
punching.
3. Device in connection to hole punching pliers according to
claim 1, characterised in that the
symmetrical axis (30) of the holding-up plate (18),
forming the rotational axis of the holding-up plate (18),

running eccentrically in relation to the symmetrical axis (26) of the hole socket (16) with regard to a position where the hole socket (16) abuts directly on the holding-up plate (18).

- 5 4. Device in connection to hole punching pliers according to
claims 1-3, characterised in that the
holding-up plate (18, 18c) having a pivotal bearing.

10 5. Device in connection to hole punching pliers according to
claims 1-4, characterised in that the
holding-up plate (18, 18c) having pivotal bearing around
its symmetrical axis (30) by means of a bolt (32), which
is secured against axial dislocation at each end (36,
40), preferably in the shape of a head part (40), which
is secured to the holding-up plate (18, 18c), and a
short, externally threaded end part (36), which after
15 being screwed through an internally threaded boring (34)
in the nose part (14) of the pliers, or through a part
connected to said nose part, is confined to an
unthreaded, closed end part (38), forming the end of sa
internally threaded boring (34).

1/5

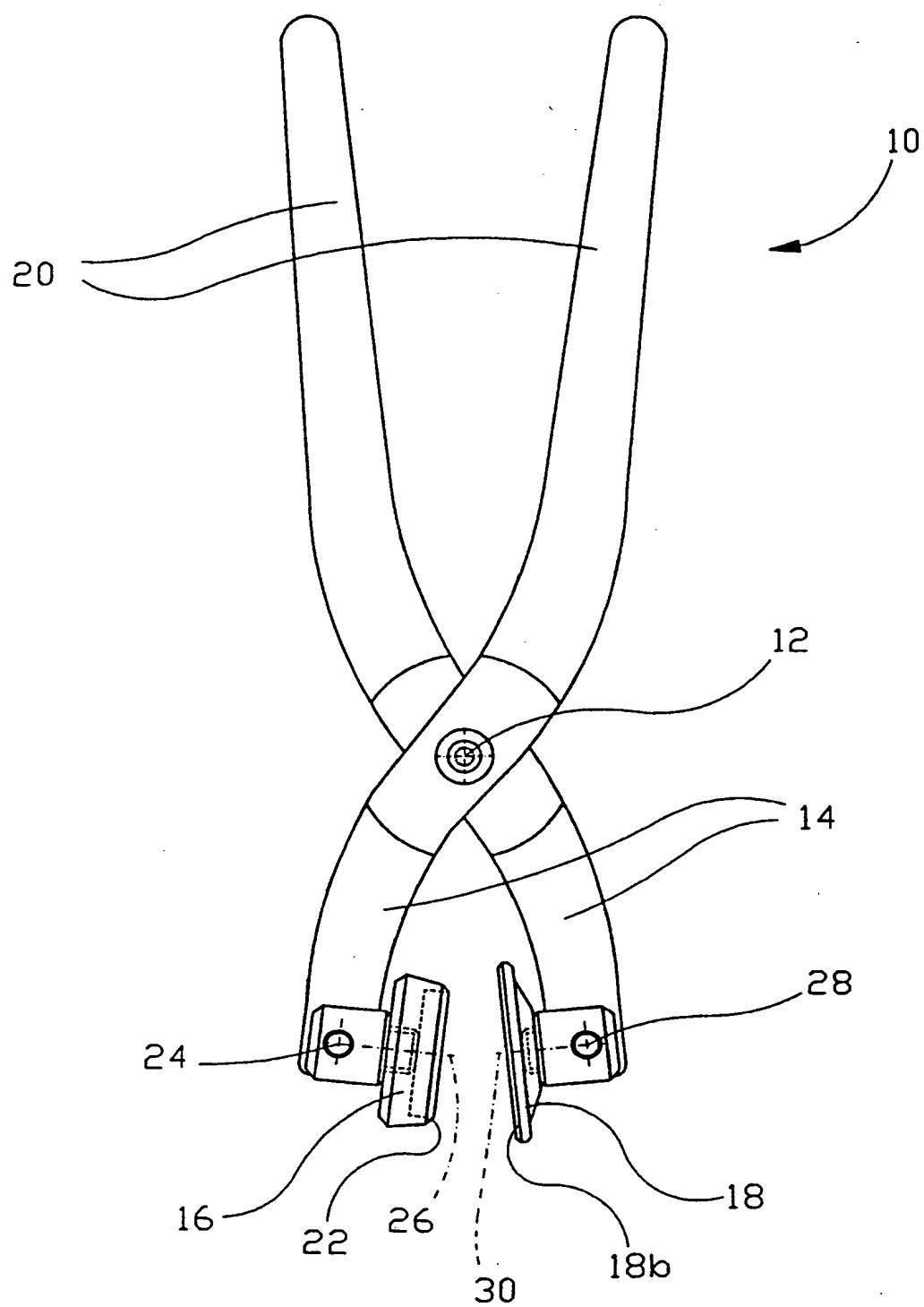


FIG. 1

2/5

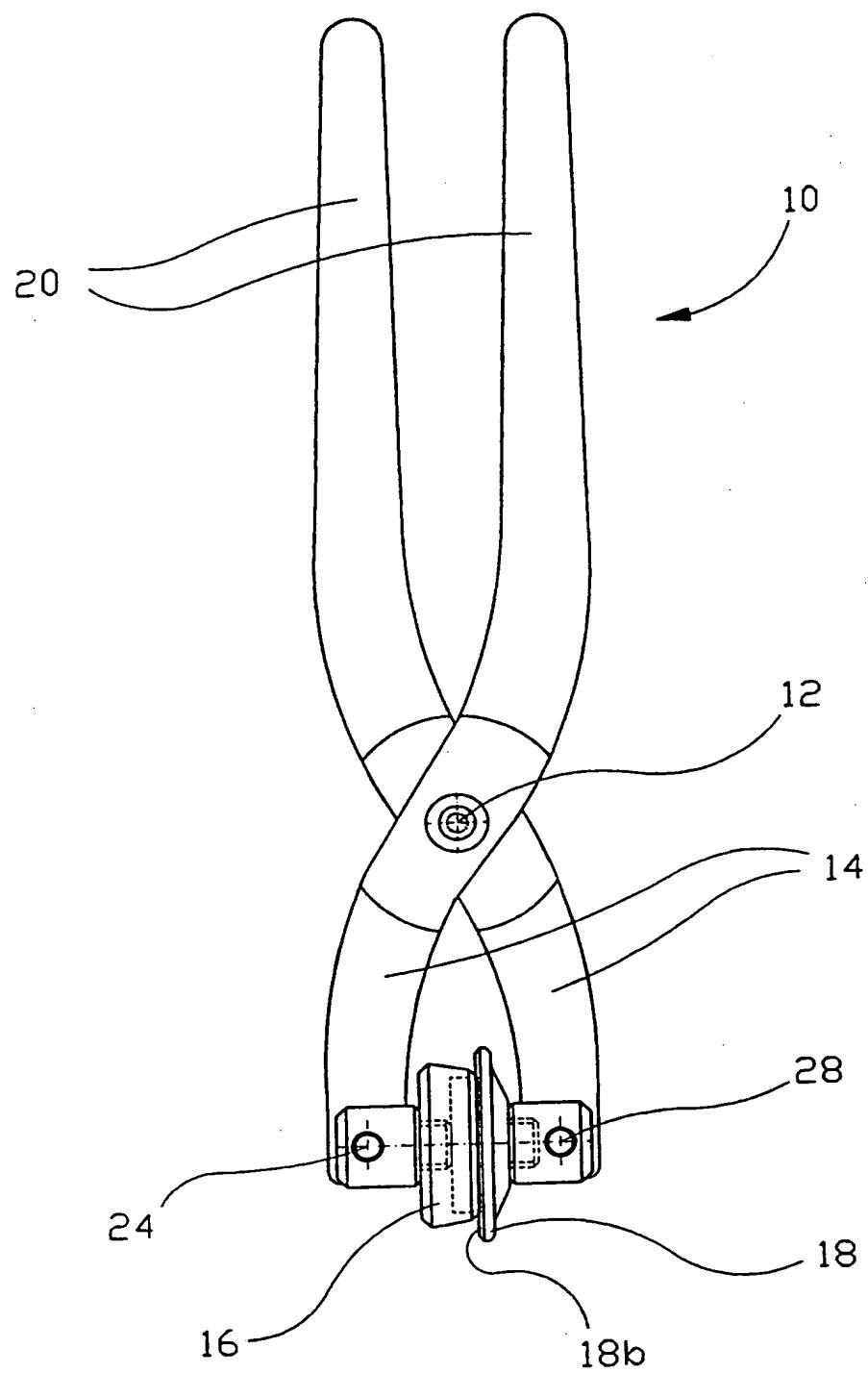


FIG. 2

3/5

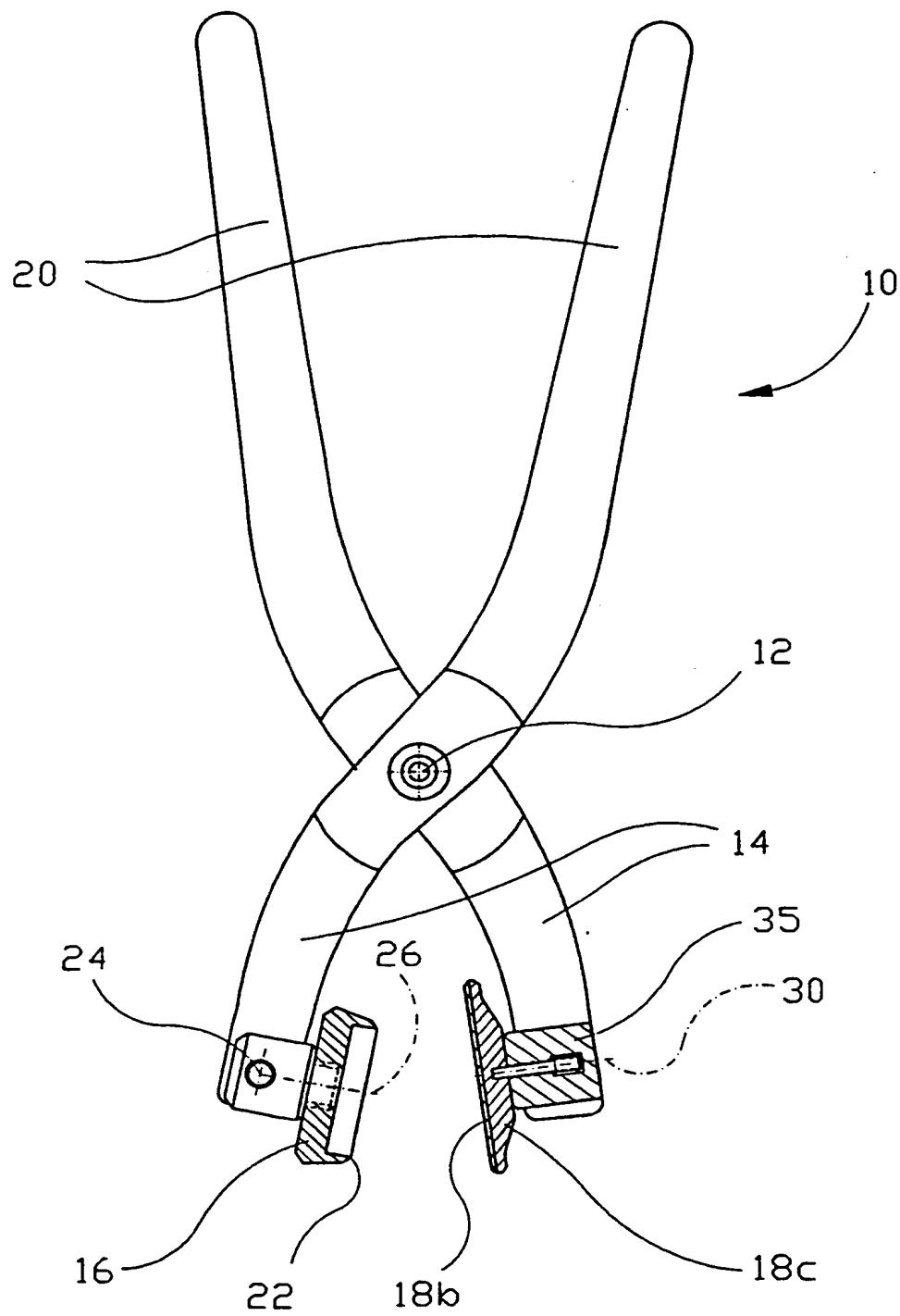


FIG. 3

4 / 5

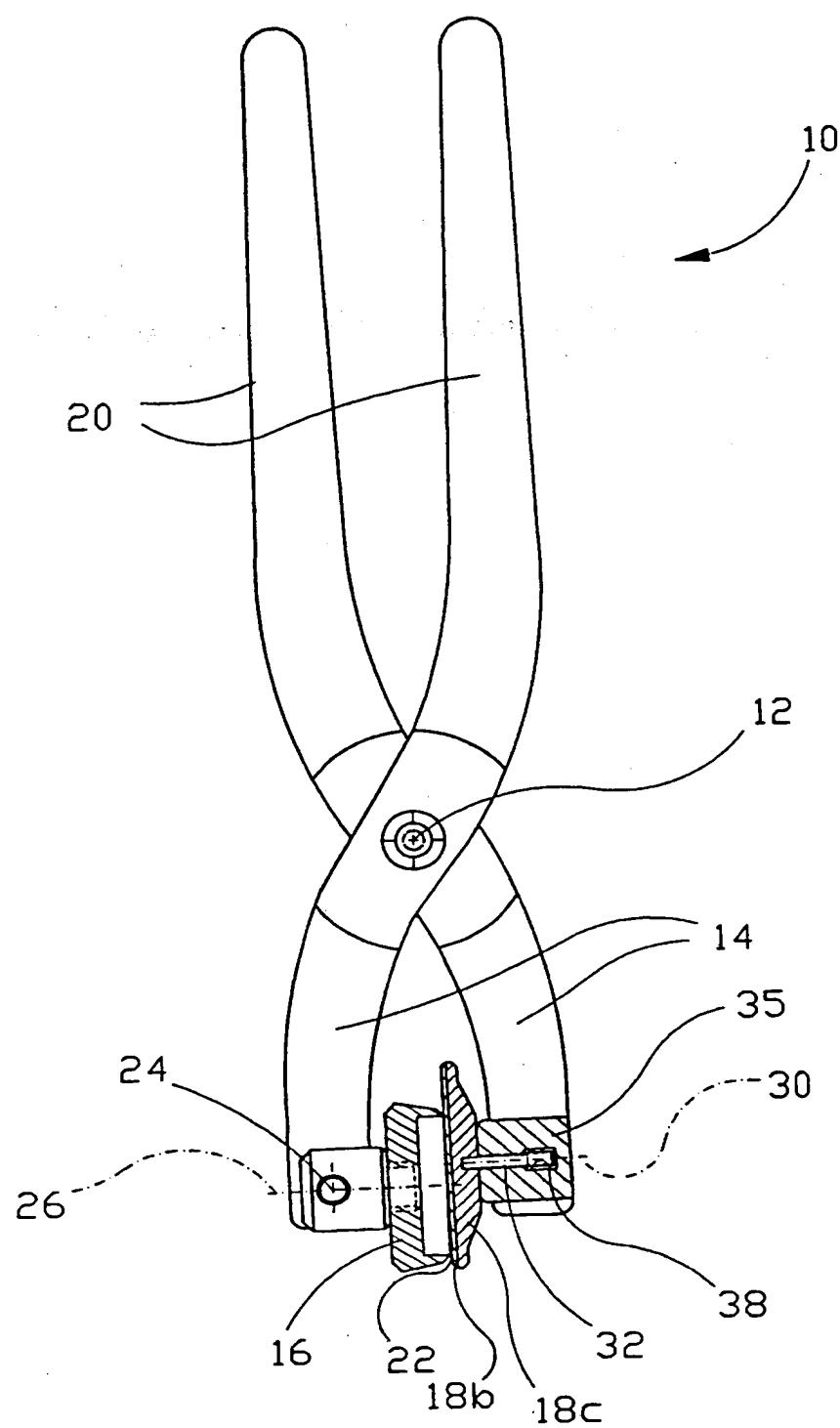


FIG. 4

5/5

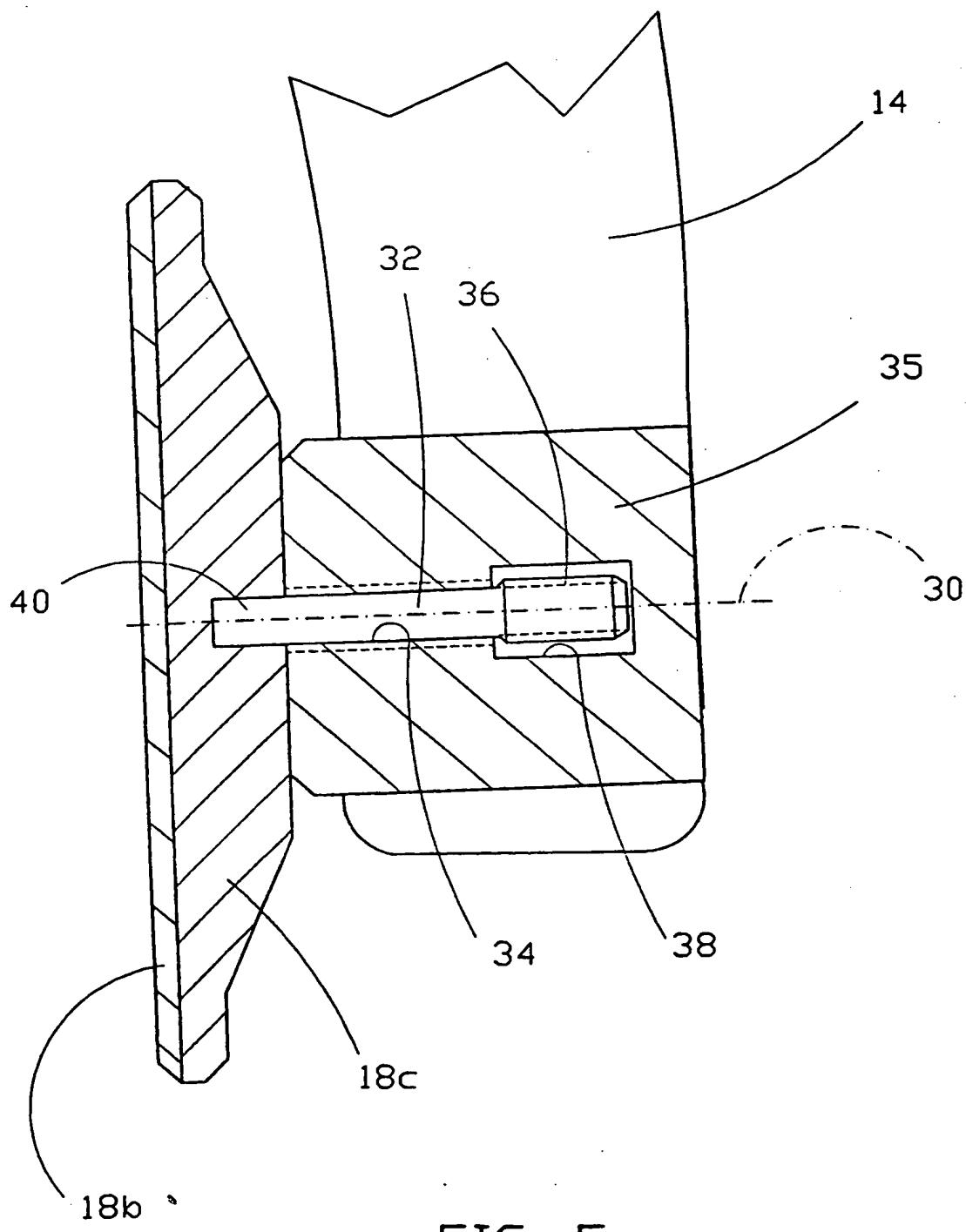


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/NO 00/00077

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 5/445, B26F 1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F, B26F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5377415 A (J. GIBSON), 3 January 1995 (03.01.95), column 5, line 31 - column 6, line 30, figure 3 --	1-2
Y	US 4817287 A (J.O. ARNOLD ET AL), 4 April 1989 (04.04.89), figures 1,6, abstract --	1-2
Y	US 5361664 A (A.R. DESMARAIS), 8 November 1994 (08.11.94), column 2, line 66 - column 3, line 12, figures 2-5 --	1-2
A	DE 19521709 A1 (NAGEL. E.), 21 December 1995 (21.12.95), figures 6-7, abstract --	1-2

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 July 2000	24-07-2000
Name and mailing address of the ISA. Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer Leif Brander / MRO Telephone No. + 46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.

PCT/NO 00/00077

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5377415 A	03/01/95	NONE	
US 4817287 A	04/04/89	NONE	
US 5361664 A	08/11/94	NONE	
DE 19521709 A1	21/12/95	DE 9409801 U	22/09/94